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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,725	07/18/2003	Frank Butaric	CRD-0836 DIV I	2936
27777 7590 02/19/2009 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
EXAMINER MILLER, CHERYL L				
ART UNIT		PAPER NUMBER		
3738				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/622,725

Applicant(s)

BUTARIC ET AL.

Examiner

CHERYL MILLER

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 line 11 recites, "there are *two peaks* between each circumferentially adjacent diamond shaped cell" which is considered new matter-exactly two peaks are not found between adjacent diamonds. Details of applicant's stent are shown in figures 4 and 8. Rings or rows of diamond cells are shown to alternate with sinusoidal rings. Between circumferentially adjacent diamonds, there appears to be either two peaks and three valleys OR three peaks and two valleys (depending on what one considers a peak and a valley). For example, if the peaks face the proximal end of the stent and the valleys face the distal end of the stent, sometimes two peaks exist between circumferentially adjacent diamonds and sometimes three peaks exist between circumferentially adjacent diamonds (not always two). Claims 2-6 depend upon claim 1 and inherit all problems associated with the claim.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not provide antecedent basis for “substantially cylindrical shaped elements”, specification instead refers to these as “hoops”. The specification also does not provide antecedent basis for “peaks and valleys”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al. (US 5,122,154, cited previously) in view of Chevillon et al. (US 2003/0065378 A1, cited previously). Referring to claim 1, Rhodes discloses a stent-graft (fig.3) comprising a hollow substantially cylindrical radially expandable stent (all 30's) having a plurality of interconnected struts (32) forming diamonds, the diamonds connected cylindrically (see figures; each ring 30 is a cylindrical shaped element), and a graft member (28) attached to the stent (30's), the graft member comprising longitudinally directed pleats (28A). Rhodes discloses a stent graft substantially as claimed, however Rhodes discloses a plurality of individual stents along the length of the graft instead of a single unitary stent. Chevillon teaches in the same field of stent-grafts, the use of a single unitary stent (5', 5"; fig.10, 11) having the stent configuration claimed (see attachment 1 provided in previous action; which shows two peaks between diamonds; the

width of two diamonds is spanned by two or three peaks of the adjacent sinusoidal ring) as an alternative to a plurality of individual stents (5; fig.1) along a length of a graft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Rhodes stent-graft having a plurality of stents, with Chevillon's teaching of using a unitary stent as an alternative to a plurality along a graft in order to provide a stent-graft of a different stent design still serving the function of supporting the vessel. Stents of various structures are well known in the art, including linked, separated, and unitary stents. It would have been obvious to substitute one stent for the other, with the use of Rhodes graft as it would be common sense Rhodes pleated graft could be used with stents of different designs such as those illustrated by Chevillon.

Referring to claim 2, Rhodes discloses the graft (28) attached to an exterior of the stents (col.6 line 66-col.7 line 1).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevillon et al. (US 2003/00653378 A1, cited previously) in view of Lunn (US 5,476,506, cited previously). Referring to claim 1, Chevillon discloses a stent-graft (fig.10, 11) comprising a single hollow substantially cylindrical radially expandable stent (5', 5") having the structure claimed (fig.10, 11; attachment 1 provided in previous action shows two or three peaks spanning the width of two circumferentially adjacent diamonds) and a graft member (3) attached to the stent (5', 5"), the stent being covered by the entire length of the graft (figures). Chevillon discloses the stent-graft substantially as claimed, however does not disclose longitudinal pleats on the graft. Lunn teaches in the same field of stent-grafts, the use of longitudinal pleats (22, 24; col.3, lines 10-15; fig.1, 2) on grafts in order to provide the graft with increased capability for expansion (col.3,

lines 42-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Chevillon's stent-graft with Lunn's teaching of longitudinal pleats on grafts, in order to provide a stent-graft with increased expansion capability, such that the stent-graft may be better tailored to the size of the patient's vessel. Longitudinal pleats on vascular graft structures are well known in the art see for example as evidence Rhodes US 5,122,154 and Trescony US 5,653,745, both cited previously.

Referring to claims 2 and 4-6, Chevillon discloses the graft (3) to cover an exterior surface of the stent (5', 5"; see fig.10, 11), the graft formed of dacron (P0056), and the stent to be self-expanding made of superelastic nickel titanium (P0061).

Referring to claim 3, Chevillon discloses attached of the stent (5") to the graft (3) by an attachment means (7), however does disclose the attachment means to be a staple (Chevillon discloses sutures instead of staples). Lunn teaches in the same field of stent graft's the use of staples as a common attachment means (col.5, lines 10-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Chevillon's in view of Lunn's stent-graft with Lunn's teaching of staples as a common attachment means, in order to provide a stent-graft attachment by an alternate means (staple instead of suture-both known to be common means for attachment in the art).

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al. (US 5,693,085, cited previously) in view Lunn (US 5,476,506, cited previously) and Milo (US 6,206,911 B1, cited previously). Referring to claim 1, Buirge discloses a single stent (10; 40; fig.1 or 3; and stents incorporated by references in US 4,954,126 and US 4,776,337 for example), and a graft (12), the stent (10) being covered by the entire length of the graft (12;

fig.1) and the stent shown to have various configuration and discloses to be any suitable stent design (col.3, lines 36-60; col.6, lines 65-67). Buirge discloses the stent-graft substantially as claimed, however does not disclose the specific stent structure claimed or the graft to have longitudinal pleats. Milo discloses an alternate stent design (see figure 3) having diamond cells (35) arranged in a cylinder (cylindrical elements) spaced by sinusoidal rings (43), two peaks at least between circumferentially adjacent diamonds (see fig.3, attachment 2 provided with previous action). Stents of various structures are well known in the art. It would have been obvious to substitute one stent for the other. Lunn teaches in the same field of stent-grafts, the use of longitudinal pleats (22, 24) on grafts (10) in order to provide an increased expansion capability (col.3, lines 10-16, 37-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Buirge's stent-graft, with Milo's teaching of an alternate stent design and with Lunn's teaching of longitudinal pleats in order to provide a stent-graft with increased capability to expand to the desired diameter of a patient's vessel. Longitudinal pleats on vascular graft structures are well known in the art see for example as evidence Rhodes US 5,122,154 and Trescony US 5,653,745, both cited previously. Stent structures with diamond cells and sinusoidal rings are also well known in the art, see Chouinard (US 6,585,758; fig.6, 7), Vargas (US 6,652,541 B1; fig.7), Culombo (US 6,190,405 B1; fig.1) for further evidence of such commonly known stent designs.

Referring to claims 2, 5, and 6, Buirge discloses the graft (12) to be attached to the exterior of the stent (fig.1), and the stent to be self-expanding nickel-titanium (col.3, lines 36-55).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738